

Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner



Indiana State Department of Health

An Equal Opportunity Employer

March 12, 2009

IN RE THE MATTER OF:

Vicki S. Farmwald
Hacienda Mexican Restaurants
1501 N. Ironwood Drive
South Bend, IN 46635

Re: Variance Request Dated September 12, 2008 and Section 195,
Reduced Oxygen Packaging (ROP); criteria

Order to Deny a Variance

You are hereby notified that based on the recommendation of the Food Protection Program, Indiana State Department of Health (ISDH), and as authorized by Indiana Code (IC) 16-19-3-4.3 and IC 16-42-5-5.2, the State Health Commissioner hereby orders that a variance be denied to Vicki S. Farmwald, Hacienda Mexican Restaurants, 1501 N. Ironwood Drive, South Bend, IN 46635.

This variance denial is based on the variance application submitted on September 12, 2008 and supplemental information provided that ensued as a result of the review. As part of the review of the variance application, an ISDH representative conducted an on-site evaluation to determine if and how the procedures put into place were being administered and monitored.

Order

This **VARIANCE DENIAL** is based on the following criteria:

1. The application was incomplete in that supporting documentation to demonstrate how your proposed plan would be implemented was not submitted. Examples of supporting documentation are, but not limited to, the following:
 - a. A complete list of foods to which ROP is applied;
 - b. The hazard analysis critical control point (HACCP) plan for each food to which ROP is applied;
2. The application references the use of the 2005 Food and Drug Administration (FDA) Model Food Code (MFC) Section 3-502.12 *Reduced Oxygen Packaging, Criteria*. Although the document has not been adopted in Indiana and is not referenced in the ISDH Retail Food Sanitation Requirements Rule 410 IAC 7-24, the use of the document was considered. However, the entire section 3-502.12(D) was not incorporated into the operation, as observed during the on-site visit and/or the standard operating procedure (SOP) submitted with the application and therefore is not valid.
 - a. The hazard analysis critical control point (HACCP) plan, in compliance with section 8-201.14 of FDAMFC, was not provided for each food to which ROP is applied;

- b. At the time of the on-site visit, the cooking temperature of the taco meat was taken by the food handler, by inserting an approximately four (4) inch probe thermometer into roughly one hundred eighty (180) pounds of taco meat. The probe was too short to check the taco meat and ensure that the appropriate internal temperature was obtained in the center of the batch.
 - c. At the time of the on-site visit, it was observed that a designated area, separate from the daily function of the restaurant, was not utilized for the ROP process exposing the taco meat to potential contaminants.
 - d. Information regarding the oxygen transmission rate of the packaging material used in the ROP process was not provided.
 - e. The cooling process, observed during the on-site visit, did not meet the cooling process delineated in section 3-502.12(D) (2)5(e). If the product is not cooled as described in section 3-502(D) (2)5(e), then "shelf-life" is not an acceptable barrier.
 - f. The refrigeration unit that the product was being stored in was not equipped with an electronic system that continuously monitors time and temperature and was not visually examined for proper operation twice daily.
 - g. The records required to confirm that cooling and cold holding refrigeration time/temperature parameters are required as part of the HACCP plan, were not maintained and made available to the regulatory authority upon request or held for six (6) months.
 - h. Written operational procedures as specified under section 3-502(B) (5) and a training program as specified under section 3-502(B) (6) were not provided and implemented.
3. If not in compliance with section 3-502.12(D) (2)5(e) of FDAMFC, then it would be necessary to comply with section 195 of ISDH 410 IAC 7-24. The following list of items were not included in your submittal:
- a. Documentation which reveals that *Clostridium botulinum* is or is not a microbiological hazard in the foods that undergo ROP in the establishment.
 - b. Documented proof of the two barriers in place to control the growth and toxin formation of *Clostridium botulinum*.
 - c. The hazard analysis critical control point (HACCP) plan, in compliance with section 115(a)(4) of 410 IAC 7-24 and section 195(b)(1-7) was not provided for each food to which ROP is applied;

If you wish to request an administrative review or stay of effectiveness of this decision pursuant to Ind. Code §4021.5-3-7(a), you must petition for such review in writing. The petition must state facts demonstrating that:

- a. you are a person to whom the decision is specifically directed;
- b. you are aggrieved or adversely affected by the decision; or,
- c. you are entitled to review under any law.

Your request for review or stay of effectiveness must be filed in writing with the State Health Commissioner, 2 North Meridian Street, Indianapolis, Indiana 46204, on or before March 30, 2009. If no request for review or stay of effectiveness is filed by March 30, 2009, this decision shall become final.

DATED AT INDIANAPOLIS, INDIANA, THIS 12th DAY OF March, 2009.

PURSUANT TO IC 16-19-3-4.3 AND IC 16-42-5-5.2, I HEREBY DENY A VARIANCE OF FOOD PROTECTION RULES AS STATED ABOVE.

JUDITH A. MONROE, M.D.
STATE HEALTH COMMISSIONER

By: 

Loren Robertson, M.S., R.E.H.S.
Assistant Commissioner
Public Health and Preparedness

cc: ISDH Food Protection Staff
Local Health Department in Indiana